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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,560	06/17/2005	Toshifumi Yamaki	1034232-000033	3894
21839	7590	06/15/2009		
BUCHANAN, INGERSOLL & ROONEY PC			EXAMINER	
POST OFFICE BOX 1404			RAMIREZ, DELIA M	
ALEXANDRIA, VA 22313-1404				
			ART UNIT	PAPER NUMBER
			1652	
			NOTIFICATION DATE	DELIVERY MODE
			06/15/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

***ADVISORY ACTION***

1. Claims 102-116 are pending.
2. The request for entering amendments to claims 102, 105-106, 109, 111, 113, cancellation of claims 103-104, 107, 108, 110, 112, addition of claims 117-119, and arguments filed on 5/15/2009 under 37 CFR 1.116 in reply to the Final Action mailed on 2/20/2009 are acknowledged. The proposed amendments to the claims will not be entered. While amendments to the claims seem to overcome the objections, the 35 USC 112, second paragraph rejections, the 35 USC 112, first paragraph rejections and the 35 USC 102(b) rejection previously applied, the proposed amendments to the claims raise new issues which would require further consideration as discussed below.
3. Proposed new claim 118 would be rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-4 of U.S. Patent No. 5807730 (common inventors Kiyoshi Ito and Toshifumi Yamaki). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. Proposed new claim 118 is directed in part to a nitrile hydratase which comprises an alpha subunit that comprises SEQ ID NO: 1 except for substitutions at positions 6, 19 and 126 of SEQ ID NO: 1, and a beta subunit that comprises SEQ ID NO: 2 except for substitutions at positions 108, 200, 212 of SEQ ID NO: 2, or substitutions at positions 108, 212 of SEQ ID NO:2.

Claim 3 of said patent is directed to a nitrile hydratase which comprises an alpha subunit which is a variant of the polypeptide of SEQ ID NO: 1 (same as SEQ ID NO: 1 of the instant application) wherein said variant results from the substitution at one or more positions selected from the group consisting of positions 6, 19, 38, 77, 90, 102, 106, 126, 130, 142, 146, 187, 194, and 203. Claim 4 of said patent is directed to a nitrile hydratase which comprises a beta subunit which is a variant of the polypeptide of SEQ ID NO: 2 (same as SEQ ID NO: 2 of the instant application) wherein said variant results from the substitution at one or more positions selected from the group consisting of positions 20,

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21, 108, 200, and 212. The specification of said patent discloses several variants which support the claimed genus of nitrile hydratases of claims 3-4 including the nitrile hydratases described in Tables 41-44 of said patent (clones # 41-44). Those nitrile hydratases comprise an alpha subunit which is a variant of the polypeptide of SEQ ID NO: 1 wherein only positions 6, 19, 126 have been substituted with other amino acids, and a beta subunit which is a variant of the polypeptide of SEQ ID NO: 2 wherein only positions 108, 212 or positions 108, 200, 212 have been substituted with other amino acids. Thus, the proteins of new proposed claim 118 of the instant application are rendered obvious in view of the variants of Tables 41-44 of the patent which have been disclosed as preferred embodiments of the nitrile hydratases of claims 3-4 of said patent.

4. As indicated in a telephonic interview with Ms Lisa Stahl on 5/14/2009 and in the Final action mailed on 2/20/2009, the Examiner indicated that claims directed to isolated cells comprising the proteins recited in claims 102, 106, 109, 113 and 118 are encompassed by those groups indicated in the restriction requirement mailed on 9/26/2007 directed to polynucleotides, plasmids, host cells and methods for recombinant production of a protein (original groups D-F). The Examiner withdrew claims directed to host cells from consideration as stated in the Final action mailed on 2/20/2009. While the Examiner indicated to Ms Stahl that if rejoined, these claims will be subjected to a double patenting rejection if presented in another application, Ms Stahl indicated to the Examiner that applicant would like to have claims 114-117, 119 examined in the instant application. While these claims remain withdrawn from consideration in view of the non-entry of the amendments, it is noted that if rejoined, new proposed claim 119 would be rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 19 of U.S. Patent No. 5910432 (common inventors Kiyoshi Ito and Toshifumi Yamaki). Claim 19 is directed in part to a transformed eukaryotic or prokaryotic cell transformed with a plasmid which encodes a variant of the alpha subunit of SEQ ID NO: 1 and a variant of the alpha subunit of SEQ ID NO: 2, wherein said variant of the alpha subunit of SEQ ID NO: 1 is one where positions 6,

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19, 126 have been substituted with other amino acids, and wherein said variant of the beta subunit of SEQ ID NO: 2 is one where positions 108, 212 or positions 108, 200, 212 have been substituted with other amino acids. The specification of U.S. Patent No. 5910432, Tables 41-44, discloses these variants as preferred embodiments of the genus of nitrile hydratases encoded by the recited plasmids. Thus, the host cell of new proposed claim 119 is deemed obvious over claim 19 of U.S. Patent No. 5910432 in view of the preferred embodiments disclosed in the specification of U.S. Patent No. 5910432.

5. If a terminal disclaimer is filed, new proposed claim 118 should be amended to recite "(a) the  $\alpha$  subunit comprises the polypeptide of SEQ ID NO: 1 except that the amino acid sequence of the polypeptide of SEQ ID NO: 1 is substituted at one or more positions selected from the group consisting of positions 6, 19.....and 204.....; and (b) the  $\beta$  subunit comprises the polypeptide of SEQ ID NO: 2 except that the amino acid sequence of the polypeptide of SEQ ID NO: 2 is substituted at one or more positions selected from the group consisting of positions 10, 20.....and 217 by another amino acid"

6. The rejections previously applied are, therefore, maintained for the reasons of record in view of the non-entry of the proposed amendments.

7. For purposes of Appeal, the status of the claims is as follows:

Claim(s) allowed: NONE

Claims(s) objected to: NONE

Claim(s) rejected: 102-113

Claim(s) withdrawn from consideration: 114-116

8. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (571) 273-8300. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be

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retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez, Ph.D., whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (571) 272-0811. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

/Delia M. Ramirez/

Primary Examiner  
Art Unit 1652

DR  
June 11, 2009